

Serial No.: 10/037,429

Attorney Docket No.: 53951-055

**REMARKS**

Claims 17, 60, 61, 70, 71, 74, 81, and 83 stand rejected under 35 USC §102 as anticipated by O'Mahoney (US 6,585,675) and claims 18, 72, and 82 stand rejected under 35 USC §103 as obvious over O'Mahoney. Applicant hereby traverses the rejections and requests that they be fully reconsidered in view of the arguments set forth below.

**Rejections under 35 USC §102**

Claim 17 stands rejected as anticipated by O'Mahoney. The Office Action states that O'Mahoney shows a leak detector that detects leaks outside the blood circuit and that the leak detector is located to detect leaks by detecting a presence of blood outside the blood circuit, the outside being a non-wetted environment of the blood circuit. The item in O'Mahoney to which the Office Action refers is (quoting the specification of O'Mahoney) "a blood leak detector 118 in the ultrafiltrate output monitors for the presence of a ruptured filter." The ultrafiltrate output is a line from which filtrate is drawn as indicated in Fig. 2 and described in O'Mahoney. This sensor is not configured as defined in claim 17. It detects blood entering a liquid environment filled with ultrafiltrate. This is a classic type of sensor which looks at color or opacity from outside the tube, but it looks into the decidedly wet inside of that tube.

Claim 60 was also rejected as anticipated by O'Mahoney in reliance on the same position as indicated in the Office action, namely, that the leak detector 118 detects a presence of blood in a non-wetted environment of the blood circuit. In addition, claim 60 also recites "a mechanism adapted to periodically generate a negative pressure in said blood circuit such that air infiltrates said blood circuit through any openings therein." In O'Mahoney, the pump reversals may or may not occur since they are responsive to pressure detected in the patient access. Thus, the reversal is not periodic so that the limitation quoted above is not met by the disclosure of O'Mahoney. Note that claim 60 was amended but only to fix an obvious typographical error and not in any way to change its scope.

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Claim 70 was also rejected as anticipated by O'Mahoney in reliance on the same position as indicated in the Office action, namely, that the leak detector 118 detects a presence of blood in a non-wetted environment of the blood circuit. In addition, claim 70 also recites "a mechanism adapted to periodically generate a negative pressure in said blood circuit such that air infiltrates said blood circuit through any openings therein." In O'Mahoney, the pump reversals may or may not occur since they are responsive to pressure detected in the patient access. Thus, the reversal is not periodic so that the limitation quoted above is not met by the disclosure of O'Mahoney.

Claim 74 was also rejected as anticipated by O'Mahoney in reliance on the same position as indicated in the Office action, namely, that the leak detector 118 detects a presence of blood in a non-wetted environment of the blood circuit. In addition, claim 74 also recites "creating a temporary negative pressure at least two times during said treatment operation in at least a second portion of said blood circuit." In O'Mahoney, the pump reversals may or may not occur since they are responsive to pressure detected in the patient access. Thus, the reversal is not such as to satisfy the quoted limitation. Also, claim 74 recites "at least one of halting a pumping of blood in either or both of said first and second blood circuit portions or generating an alarm signal" which the Office Action states is disclosed in claim 1-11. Claims 1-11 do not describe this limitation. It is true that an infusion alarm is indicated as generated, but this is in response to detection of a pressure state, not to the detection of air as recited in the claim. Also the pump reversals are also in response to the detection of a pressure state. Clearly, the limitation quoted above is not met by the cited disclosure of O'Mahoney.

Claim 81 was also rejected as anticipated by O'Mahoney in reliance on the same position as indicated in the Office action, namely, that the leak detector 118 "detects leaks by sensing liquid in an otherwise dry outside environment of said blood treatment circuit." In addition, claim 81 also recites "insures that at least part of said lines are under negative pressure at least part of the time during a treatment such that a detectable air or bubble infiltration indicates a presence of a leak in said lines." In O'Mahoney, the pump

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reversals may or may not occur since they are responsive to pressure detected in the patient access. Thus, the reversal described in the disclosure of O'Mahoney does not meet the limitation quoted above.

Given that claims 17, 60, 61 which depends from 60, 70, 71, which depends from 70, 74, and 81, each contain at least one element that was not shown in the reference, the rejection over O'Mahoney cannot stand and Applicant requests that the rejections therefore be withdrawn.

Rejections under 35 USC §103

Claims 18, 72, and 82 stand rejected as obvious over O'Mahoney. Applicant submit that since the rejections of claim 17, 72, and 82 rely on the premise of anticipation of their base claims and since the base claims were not properly rejected, the rejections of these claims for obviousness is rendered moot. Applicant also requests that if the Examiner chooses not to withdraw the rejections of claims 18, 72, and 82, that documentary evidence of obviousness, in the context defined by the claims, of the limitations of claims 18, 72, and 82 be provided. Also, Applicant also requests that a basis for the rejection under the law and rules governing Patent Office practice rejection based on the position that the inventions "do not provide any advantage nor improvement over the prior art nor does their implementation provide any unexpected result in view of the prior art." Applicant submits that these are not proper bases for rejection under section 103.

If the Examiner wishes to discuss any issues relating to the present application, the Examiner is invited to call the undersigned attorney at 202 778 1118.

Respectfully submitted,

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